PONVORY®▼(ponesimod) PATIENT/ CAREGIVER GUIDE

Important things to remember about PONVORY® (ponesimod) treatment

Adverse events should be reported. ▼This medicinal product is subject to additional monitoring and it is therefore important to report any suspected adverse events related to this medicinal product.

Healthcare professionals are asked to report suspected adverse events via: HPRA Pharmacovigilance Website: www.hpra.ie. Adverse events should also be reported to Janssen Sciences Ireland UC on 1800 709 122 or email dsafety@its.jnj.com

For further information please contact Janssen Medical Information at:
Tel: 1800 709 122
Email: medinfo@its.jnj.com

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Marketing authorisation holder: Janssen-Cilag International NV, Turnhoutseweg 30, B-2340 Beerse, Belgium

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PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Introduction

- This guide contains important information which is essential to ensure the safe and effective use of PONVORY® and appropriately manage important selected risks
- It covers dosing, side effects, identified and potential risks, and includes guidance relating to pregnancy
- Read this guide and the patient information leaflet which is inside your PONVORY® medication package thoroughly before you start your treatment. Keep this guide together with the patient information leaflet as you may need to refer to it during treatment

PONVORY® should not be used during pregnancy or if you are of childbearing potential and not using effective contraception, due to risk of harmful effects to the fetus. If you are of childbearing potential, you will also be given a Pregnancy Reminder Card for further information; please read this card as it contains important information.

What is PONVORY®, what is it used for, and how does it work?

What is PONVORY®?

PONVORY® contains a medicine called ponesimod. It belongs to a group of medicines known as sphingosine-1-phosphate receptor modulators.

What is PONVORY® used for?

PONVORY® is used to treat adults with relapsing multiple sclerosis with active disease.

What is multiple sclerosis?

Multiple sclerosis (MS) is a long-term autoimmune disease that affects the nerves in the brain and spinal cord, which together are known as the central nervous system.

- Normally, a protective layer called myelin covers the nerve fibres in the central nervous system
- In MS, the body's immune system mistakenly attacks the protective layer of myelin, causing inflammation and damage. This breakdown in the myelin stops the nerves from working properly and results in the range of symptoms seen in MS

Relapsing MS is a type of MS where these attacks on myelin are repeated (known as relapses) causing symptoms to occur. These symptoms may disappear completely after the relapse, but some symptoms may remain due to permanent damage to the nervous system.

How does PONVORY® work?

PONVORY® reduces the number of circulating lymphocytes which are white blood cells involved in the immune system. It does this by keeping them in the lymphoid organs (lymph nodes). The exact mechanism by which PONVORY® exerts its therapeutic effect is unknown but it may involve the reduction of lymphocytes available to attack the myelin sheath around the nerves in the brain and spinal chord. Decreasing nerve damage in patients with MS reduces the number of attacks (relapses) and slows down worsening of the disease.

Starting treatment with PONVORY®

Heart monitoring

- Before you start treatment, your doctor will check your heart using an electrocardiogram (ECG). This is to determine if you have any existing heart conditions. For certain heart conditions, your doctor will monitor you for at least 4 hours after your first dose of PONVORY®
- You should tell your doctor immediately if you experience any signs or symptoms of a slow heart rate (such as dizziness, vertigo, nausea or palpitations) after your first dose of PONVORY®

Vaccinations

- Your doctor will check whether you are protected against chickenpox. If you are not, you may need to have the chickenpox vaccination at least 4 weeks before starting treatment with PONVORY®

Blood tests

- Before starting treatment your blood may be tested to check your blood cell count and your liver function, if these have not been measured recently (within the last 6 months)
- Blood testing may also be required after stopping prior therapy

Vision

- Before starting treatment, your doctor will check your vision and examine the back of your eye

Seizure/Epilepsy

- Before starting treatment, you should tell your doctor if you have ever experienced a seizure or have a family history of epilepsy

Starting treatment with PONVORY®

Treatment initiation

- Your treatment with PONVORY® will start with a 14-day treatment initiation pack. You should follow the 14-day titration schedule as outlined below and within the 14-day treatment initiation pack:

Titration day	Daily dose
Day 1 and 2	2 mg
Day 3 and 4	3 mg
Day 5 and 6	4 mg
Day 7	5 mg
Day 8	6 mg
Day 9	7 mg
Day 10	8 mg
Day 11	9 mg
Day 12, 13 and 14	10 mg

- After dose titration is complete, the recommended maintenance dosage of PONVORY® is 20 mg taken orally once daily starting on Day 15; a maintenance pack is required
- A dose titration is recommended for initiation of PONVORY® treatment to help reduce cardiac effects; PONVORY® may result in a transient decrease in heart rate and atrioventricular conduction delays

While you are taking PONVORY®

Treatment interruptions

- You need to tell your doctor **if you miss 4 or more consecutive days** of PONVORY®. You should not restart PONVORY® treatment without talking to your doctor, as you will need to restart treatment with a new treatment initiation pack and an ECG should be performed by your doctor

Blood pressure

- Your blood pressure will be checked regularly while you are taking PONVORY®

Infection

- Tell your doctor immediately about any signs or symptoms of infection (such as fever, or flu-like symptoms) while you are taking PONVORY® and for up to 1 week after stopping treatment

Visual symptoms

- Tell your doctor immediately about any changes to your vision while taking PONVORY® and for up to 1 week after stopping treatment

Liver impairment

- Tell your doctor immediately about any signs or symptoms of liver impairment (such as nausea, vomiting, stomach pain, tiredness, loss of appetite, yellowing of the skin or whites of the eyes, or dark urine) while you are taking PONVORY®

While you are taking PONVORY®

Breathing problems

- Tell your doctor immediately about any signs or symptoms of new or worsening breathing problems (such as shortness of breath) whilst you are taking PONVORY®

Skin cancer

- Skin cancers have been reported in patients treated with PONVORY®
- Tell your doctor immediately if you develop any skin nodules (such as shiny, pearly nodules), patches or open sores that do not heal within the usual timelines (weeks of developing). Other symptoms of skin cancer may include abnormal growth or changes in skin tissue (such as unusual moles) with a change in colour, shape or size over time
- You should limit your exposure to sunlight and ultraviolet light; for example, by wearing protective clothing and regularly applying sunscreen with a high sun protection factor

Neurological changes

- Tell your doctor immediately if you develop any signs or symptoms of neurological changes (such as sudden severe headache, sudden confusion, sudden loss of vision or other changes in vision, or seizure) while taking PONVORY®

Women of Childbearing Potential

- Do not use PONVORY® during pregnancy, while breastfeeding, or if you are of childbearing potential and not using effective contraception
- Before starting treatment with PONVORY®:
  - Your doctor will explain the risks of harmful effects to the unborn baby if you become pregnant while on treatment, both before you start PONVORY® and regularly thereafter
  - You must have a negative pregnancy test confirmed by your doctor
- You must be using effective contraception during treatment and for at least 1 week after stopping treatment with PONVORY®. Talk to your doctor about reliable methods of contraception
- If you stop taking PONVORY® due to pregnancy or while attempting to conceive, your MS symptoms may return. This will be explained to you by your doctor
- You must tell your doctor immediately if you become pregnant while taking PONVORY® and for up to 1 week after stopping treatment
- You must immediately stop treatment with PONVORY® if you become pregnant
- Refer to the pregnancy-specific patient reminder card for further information and guidance related to contraception, pregnancy and breastfeeding

Reporting of side effects

PONVORY® is a new medicine and its safety is being closely monitored. Contact your doctor, pharmacist or nurse if you experience side effects with any medication you are taking. This includes any side effects that are not listed on the information leaflet that comes with this medication.

Reporting information: www.hpra.ie

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